

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-010

21-246 / S-007

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA		1. ORGANIZATION	2. NDA NUMBER
CHEMIST'S REVIEW		HFD-530	21-087 / SLR-010 21-246/SLR-007
3. NAME AND ADDRESS OF APPLICANT (City and State)		4. AF NUMBER	
Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902		5. DOCUMENT(S)	
		NUMBER(S)	DATE(S)
		N21-087/SLR-010	09/14/01
		N21-246/SLR-007	09/11/01
6. NAME OF DRUG		7. NONPROPRIETARY NAME	
Tamiflu capsules and oral suspension		Oseltamivir phosphate capsules and oral suspension	
8. SUPPLEMENT(S) PROVIDES FOR:		9. AMENDMENTS AND OTHER	
Revisions to the suspension sections of the consolidated capsule and suspension package insert that reflects the new 60-ml bottle size for the suspension.		<i>(Reports, etc.)</i> DATES	
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)	
Treatment of influenza A and B	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	_____, NDA 21-246	
13. DOSAGE FORM(S) capsule	14. POTENCY(IES)	75 mg/ capsule, 12 mg/ml suspension	
15. CHEMICAL NAME AND STRUCTURE		16. MEMORANDA	
See current package insert			
17. COMMENTS			
These supplements contain the revisions to the consolidated package insert (containing both capsules and suspension) in NDA 21-087/SLR010 and in the supplement to the suspension NDA (N21-246/SLR007). The following changes have been made:			
			
18. CONCLUSIONS AND RECOMMENDATIONS			
The CMC information to support these labeling changes was provided in supplement SCS006 to NDA 21-246. There are no chemistry, manufacturing or controls concerns with the current supplement SLR-010 to NDA 21-087 and it is recommended that the supplement be approved.			
19. REVIEWER			
NAME	SIGNATURE	DATE COMPLETED	
Dan Boring	<i>/see electronic signature/</i>	03/22/02	
20. CONCURRENCE: HFD-530/DNDC-830/SMiller <i>/see electronic signature/</i>			

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Dan Boring
3/26/02 10:36:43 AM
CHEMIST

Stephen Paul Miller
3/29/02 04:49:31 PM
CHEMIST